

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Lam et al.

Serial No.: 09/724,868

Filed: November 28, 2000

For:

ANTIBODY FORMULATION

Group Art Unit: 1644

Examiner: M. Dibrino

Confirmation No. 8389

Customer No. 09157

I hereby certify that this transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE, Commissioner for Patents, P.O. Box 1450, Alexandria Virginia 22313-1450 on:

March 4, 2005

Janet Tse

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)

Mail Stop ISSUE FEE
COMMISSIONER FOR PATENTS
P.O.BOX 150
Alexandria, VA 22313-1450

Dear Sir:

Applicants request reconsideration of the Director's determination of patent term adjustment (PTA) as communicated in the Notice of Allowance mailed on December 7, 2004. In particular, applicant requests restoration of 107 days of PTA erroneously charged against applicant under 37 C.F.R. § 1.704(b).

This application is filed concurrently with the payment of the Issue Fee and is therefore timely. The Director is authorized to charge applicant's Deposit Account No. 07-0630 for the required fee as specified in § 1.18(e) (\$200.00).

Facts

- 1. Attached is a printout of the Office's determination of PTA for this application, as provided on PAIR. The net PTA shown on the printout is 370 days.
- 2. (§ 1.705)(2)(i) For the following reasons, the correct PTA to which this application is entitled is 477 days.
- 3. (§ 1.705)(2)(ii). The examination delays under §§ 1.702(a) and 1.703, which are correctly shown on the attached PAIR printout, are the following:
 - 490 days for failing to mail the Restriction Requirement within 14 months of filing, for the interval between November 28, 2000 and June 2, 2003.

The sum of these delays is $490 \text{ days } (\S 1.703(f))$.

- 4. (§ 1.705)(2)(iii) This application is not subject to a terminal disclaimer.
- 5. (§ 1.705)(2)(iv)(A) The reductions under § 1.704 as shown on the attached PAIR printout which applicant believes to be correct are the following:
 - 13 days for failing to file a Response to a Non-Final Office Action within three months, for the interval between September 3, 2004 and September 16, 2004.

The sum of this delay is 13 days.

- 6. The PAIR entry for an Information Disclosure Statement (IDS) on May 28, 2004 does not correspond to a failure by the applicant to engage in reasonable efforts to conclude prosecution.
 - (a) On February 13, 2001, applicant filed an IDS in compliance with 37 C.F.R. § 1.97 and 1.98. Attached is a postcard returned to the applicant and stamped by the Office indicating that the Office did in fact receive the IDS.
 - (b) On May 28, 2004, the examiner contacted applicant by phone and indicated that she was reviewing the IDS but could not read the copy scanned into the Office's Image File Wrapper system. At the examiner's express request, applicant faxed a copy of the IDS previously filed on February 13, 2001 to the examiner (copies attached herewith).

(c) The papers filed on May 28, 2004 were identical to the IDS filed on February 13, 2001. However, these papers were erroneously entered into the PALM database as a new or supplemental IDS.

Discussion

Applicant believes that the act of filing a duplicate copy of a paper previously submitted to comply with an examiner's request does not constitute a failure to engage in reasonable efforts to conclude prosecution. In this instance, the IDS in question was first properly filed on a date which, under PTO rules and practice, did not result in such a failure. Accordingly, the submission of the papers filed on May 28, 2004 should not result in a reduction of PTA under § 1.704.

The duplicate IDS was not a submission to rectify an omission in an earlier filing $(\S 1.704(c)(7), a \text{ supplemental reply } (\S 1.704(c)(8)), or a new IDS falling outside the exception of § 1.704(d). Instead, it contained only copies of papers already filed with the Office, provided for the examiner's convenience and at the examiner's request.$

The proper treatment of the submission is indicated in the discussion of § 1.704(c)(8) at M.P.E.P. § 2732, which states that "[§] 1.704(c)(8) does not apply to a supplemental reply or other paper that was expressly requested by the examiner." For an expressly requested amendment, for example, "the examiner will have the paper processed so that it is included as part of an interview summary or examiner's amendment and not a separate paper for PALM to flag in the patent term adjustment calculation." M.P.E.P. 8th ed., Rev. 2, at 2700-20, paragraph bridging columns.

The same procedure should have been followed with the papers submitted on May 28, 2004. Because the papers were expressly requested by the examiner, and because they did not constitute any new action corresponding to a failure to engage in reasonable efforts to conclude prosecution, the PALM entry indicating that the submission was a new IDS was in error.

Conclusion

Applicant respectfully requests correction of the Office's records and adjustment of the Office's calculation of term adjustment by the addition of 107 days of patent term adjustment.

Respectfully submitted, GENENTECH, INC.

Date: March 4, 2005

By: Lee K. Tan, Ph.D.

Reg. No. 39,447

Telephone No. (650) 225-4462





United States Patent and Trademark Office

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PATENT APPLICATION INFORMATION RETRIEVAL





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Patent Term Adjustment (PTA) for application number: 09/724,868					
,			Days		
Filing or 371(c) Date:	11-28-2000	USPTO Delay (PTO):	490		
Issue Date of Patent:	-	Three Years:	-		
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL):	120		
Post-Issue Petitions (days):	+0	Total PTA:	370		
USPTO Adjustment (days):	+0	Explanation of Calculations			

Select Search Option

	Continuity Data
	File History
1	Image File Wrapper
	Publication Review

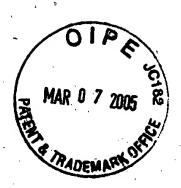
Search

Patent Term Adjustment History					
Date	Contents Description	PTO (days)	APPL (days)		
12-07-2004	Mail Notice of Allowance				
	Issue Revision Completed				
12-07-2004	Notice of Allowance Data Verification Completed				
12-07-2004	Notice of Allowability				
09-16-2004	Substitute Specification Filed				
09-16-2004	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received				
09-27-2004	Date Forwarded to Examiner				
09-16-2004	Response after Non-Final Action		13		
09-16-2004	Request for Extension of Time - Granted		1		
09-16-2004	Workflow incoming amendment IFW		Û		
05-28-2004	Information Disclosure Statement (IDS) Filed		107		
06-03-2004	Mail Non-Final Rejection				
06-01-2004	Non-Final Rejection		Û		
02-21-2004	Date Forwarded to Examiner		î		
02-11-2004	Response to Election / Restriction Filed		î		
02-11-2004	Request for Extension of Time - Granted				
12-09-2003	Mail Restriction Requirement				
12-08-2003	Requirement for Restriction / Election				
09-17-2003	Date Forwarded to Examiner				
08-11-2003	Response to Election / Restriction Filed				
08-11-2003	Request for Extension of Time - Granted				
06-05-2003	CRF Is Good Technically / Entered into Database				



06-02-2003	Mail Restriction Requirement	490	
06-02-2003	Requirement for Restriction / Election		
03-04-2003	Case Docketed to Examiner in GAU		
03-04-2003	Dispatch from OIPE to Corps - U-P-R-D Application	0	
01-18-2001	Correspondence Address Change	Û	
12-18-2000	IFW Scan & PACR Auto Security Review	1	
11-28-2000	Initial Exam Team nn		

|.HOME|INDEX|SEARCH|@BUSINESS|CONTACT US|PRIVACY STATEMENT



In re Application of: Lam et al. Serial No.: 09/724,868 Filed On: 28 November 2000 Mailed On: February <u>/3</u>, 2001 Docket No.: P1089R1C1 By: Lee K. Tan Reg. No.: 39,447

The following has been received in the U.S. Patent Office on the date stamped:

x Information Disclosure Statement

PTO 1449 Form (-0- copies of references enclosed)

x Certificate of Mailing

In re Application of: Lam et al. Serial No.: 09/724,868 Filed On: 28 November 2000 Mailed On: February <u>13</u>, 2001 Docket No.: P1089R1C1 By: Lee K. Tan Reg. No.: 39,447



The following has been received in the U.S. Patent Office on the date stamped:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Lam et al.

Serial No.: 09/724,868

Filed: 28 November 2000

For: ANTIBODY FORMULATION

Group Art Unit: Unassigned

Examiner: Unassigned

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on

February <u>13</u>, 2001

Ann Savelli

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

[x] 37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); or
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491, or
- before the mailing of the first Office action on the merits; or
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

[] 37 CFR §1.97(c)

• by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

[] 37 CFR §1.97(d)

• after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- [] 37 CFR §1.97(e) Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- [] 37 CFR §1.704(d) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- [] The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. <u>09/097,171</u>, filed <u>June 6, 1998</u> and relied upon in this application for an earlier filing date under 35 USC §120.

[] BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

- [x] not given
- given for each listed item
- [] given for only non-English language listed item(s) [Required]

[] in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,

GENENTECH, INC.

Date: February <u>13</u>, 2001

PATENT TRADEMARK OFFICE

By: Ul lan

Lee K. Tan

Reg. No. 39,447

Telephone No. (650) 225-4462

FORM PTO-1448

MAR 0 7 2005

LIST OF DISCESSURES CITED REPAPPLICANT

(Use several steeps if pages 17)

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No. P1089R1C1

Serial No. 09/724,868

Applicant

Lam et al.

Filing Date
28 Nov 2000

Group Unassigned

U.S. PATENT DOCUMENTS

Examiner		T	Τ	1		<u> </u>	<u> </u>
Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	4,093,606	06.06.78	Coval, M.		-	· · · · · · · · · · · · · · · · · · ·
	* 2	4,457,916	03.07.84	Hayashi et al.			
	* 3	4,499,073	12.02.85	Tenold, R.			
ļ	* 4	4,877,608	31.10.89	Lee, T. et al.			
	* 5	4,940,782	10.07.90	Rup et al.			
	* 6	5,032,405	16.07.91	Huang, H. et al.			
	* 7	5,036,049	30.07.91	Audhya, T. et al.			
	* 8	5,096,885	17.03.92	Pearlman et al.			
	* 9	5,147,637	15.09.92	Wright et al.			
	*10	5,149,653	22.09.92	Roser			
	*11	5,215,743	01.06.93	Singh, M. et al.			
	*12	5,262,296	16.11.93	Ogawa, E. et al.			
	*13	5,307,640	03.05.94	Fawzy et al.		,	
	*14	5,399,670	21.03.95	Bhattacharya, P. et al.			
	*15	5,506,342	09.04.96	Reno et al.			
	*16	5,580,856	03.12.96	Prestrelski et al.			
	*17	5,589,167	31.12.96	Cleland et al.			
	*18	5,608,038	04.03.97	Eibl et al.			
	*19	5,654,403	05.08.97	Smith et al.			
	*20	5,730,980	24.03.98	Ulevitch et al.			
	*21	5,736,137	07.04.98	Anderson et al.			
	*22	5,770,700	23.06.98	Webb et al.			•

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Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	n No
	*23	AU-B-30771/89	07.09.89	AUSTRALIA				
	*24	2,138,853	29.06.95	CANADA		Ì		
	*25	303,746	22.02:89	EPO				
•	*26	391,444	10.10.90	EPO				
	*27	661,060	05.07.95	EPO (WITH ENGLISH ABSTRACT)				
	*28	WO 89/09402	05.10.89	PCT (WITH ENGLISH ABSTRACT)				
	*29	WO 89/11297	30.11.89	PCT				
	*30	WO 90/11091	04.10.90	PCT				
	*31	WO 92/22653	23.12.92	PCT				
	*32	WO 94/11026	26.05.94	PCT				
	*33	WO 94/26302	24.11.94	PCT				
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Examiner

Date Considered

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

*43

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

U.S. Dept. of Commerce

Patent and Trademark Office

Atty Docket No.	Serial No.
P1089R1C1	09/724,868
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Applicant

Lam et al.

Filing Date 28 Nov 2000 Group Unassigned

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nitials ————		Document Number	Date	Country	Class	Subcias	55 165	140
	*34	WO 96/41164	19.12.96	PCT				İ
	*35	WO 97/04801	13.02.97	PCT				
	*36	WO 97/04807	13.02.97	PCT				
	*37	WO 97/17087	15.05.97	PCT		a.		
			OTHER DISCI	OSURES (Including Author, Title, Date, I	Pertinent Pages, etc	c.)	•	
	*38			selecting antimicrobial preservation chnology pps. 36-40;43-44;46 (May	-	arentera	al product	•
,	*39	Albelda et al., "	Integrins and	other cell adhesion molecules" FA	ASEB-J 4(11):286	8-2880	(1990)	· · · · · · · · · · · · · · · · · · ·
	*40	8(3):285-291 (199)1)	it Interactions in Pharmaceutical				
	*41			ein Formulations: Investigation of Res. 12:2-11 (1995)	Surfactant Eff	ects by	a Novel EF	R
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*48 Polymers" Proceed. Intern. Symp. Control. Rel. Bioact. Mater. 22:514-515 (1995)

Cleland et al., "Mechanisms of Nonionic Surfactant Stabilization of Proteins" Pharmaceutical Research (Abstract #BIOTEC 2012; Ninth Annual Meeting of the American Association of Pharmaceutical Scientists held in San Diego, CA on November 6-10, 1994) 11(10 Suppl.):S73 (1994)

Cleland et al., "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, *50 Deamidation, and Oxidation" <u>Critical Reviews in Therapeutic Drug Carrier Systems</u> 10(4):307-377 (1993)

Draber et al., "Stability of Monoclonal IgM Antibodies Freeze-Dried in the Presence of Trehalose" Journal of Immunological Methods 181(1):37-43 (1995) *51

Hernandez et al., "Role of neutrophils in ischemia-reperfusion-induced microvascular injury" Am. J. Physiol. 253(3 Pt 2):H699-H703 (1987) *52

Hildreth et al., "A Human Lymphocyte-associated Antigen Involved in Cell-mediated Lympholysis" European Journal of Immunology 13:202-208 (1983)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORMPIC	0.S. Dept. of Comm	erce	Ally Docket No.	Senai No.
	Patent and Trademark	Office	P1089R1C1	09/724,868
LICTOF			Applicant	
LISTOFT	DISCLOSURES CITED BY APPLICANT		Lam et al.	-
(Use s	everal sheets if necessary)		Filing Date	Group
			28 Nov 2000	Unassigned
	OTHER DISCLOSURES (Including Author, Titl	e, Date,	Pertinent Pages, etc.)	
*54	Hildreth et al., "The human lymphocyte function-associated differentiation antigen (HMac-1): functional effects of simmunol. 134:3272-3280 (1985)			
*55	Hynes, "Integrins: versatility, modulation, and signaling	g in ce	ll adhesion" <u>Cell</u> 69)(1):11-25 (1992)
*56	Izutsu et al., "The effects of additives on the stability elevated temperature" Intl.J.Pharmaceutics 71:137-146 (eeze-dried β-galacto	sidase stored at
*57	Jutila et al., "Inflammation-induced endothelial cell adh monocytes" <u>Transplantation</u> 48(5):727-731 (1989)	nesion	to lymphocytes, neut	rophils, and
*58	Kossiakoff, A.A., "Tertiary Structure Is a Principal Dete 240:191-194 (1988)	erminan	t to Protein Deamida	ition" <u>Science</u>
*59	Lam et al., "Microencapsulation of Recombinant Humanized American Association of Pharmaceutical Scientists, Wester (Abstract #F-22 and poster presented at the meeting) (Apr	n Regi	onal Meeting, South 25, 1997)	San Francisco, CA
*60	Lam et al., "Microencapsulation of Recombinant Humanized Proceedings of the 24th International Symposium on Contro (June 15-19, 1997) Lam et al., "Pitfalls in Development of Multi-Dose Liquid	olled Ro	elease of Bioactive	<u>Materials</u> 24:759-76
*61		act #1	37 and slides presen	nted) (March 24-28,
*62	Biochemistry 34(17):5762-5772 (1995)		-	
*63	Manning et al., "Stability of Protein Pharmaceuticals" Ph	arm. Re	<u>es.</u> 6(11):903-918 (1	989)
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*66	Novak et al., "The tolerance and safety of intravenously methylprednisolone sodium succinate formulations in norma Pharmacology.23(1):54-61 (Sep 1972)		_	
*67	Pearlman et al., "Analysis of Protein Drugs" <u>Peptide and</u> Marcel Dekker, Inc., Chapter 6, pps. 247-301 (1991)	Proteir	Drug Delivery, Vin	cent H. L. Lee,
*68	Picken et al., "Nucleotide sequence of the gene for heat- Infection and Immunity 42(1):269-275 (1983)	stable	enterotoxin II of E	scherichia coli"
*69	Pikal et al., "The Effects of Formulation Variables on the Hormone" Pharm. Res. 8:427-436 (1991)	e Stabi	lity of Freeze-Drie	d Human Growth
*70	Pikal, M., "Freeze-Drying of Proteins, Part 2: Formulation	n Selec	tion" <u>Biopharm.</u> 3(9):26-30 (1990)
*71	Rao and Kroon, "Orthoclone OKT3: Chemical Mechanisms and I Therapeutic Monoclonal Antibody" <u>Stability and Characteri</u> : <u>Histories</u> , eds. John Wang and Rodney Pearlman, New York:P.	<u>zation</u> lenum F	of Protein and Pept Press pps. 135-158,	ide Drugs: Case chapter 4, (1993)
*72	Reilly et al., "Oral delivery of antibodies: future pharms 32(4):313-323 (1997)	acokine	tic trends" <u>Clin. P</u>	narmacokinet.
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FORM PTO-1	449	U.S. Dept. of Commerce	Atty Docket No.	Serial No.
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LIST OF DIS	CLOSURES CITED BY APPLICANT		Lam et al.	-
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	OTHER DISCLOS	SURES (Including Author, Title, Date,	Pertinent Pages, etc.)	
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*74	Springer, T., "Adhesion receptors	of the immune gyatemil National	346,425,424,(1000)	
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	Steele et al., "Functional Capaci Journal of Clinical Microbiology		tions and the F(ab')2 split product"
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* 78	Vedder et al., "A Monoclonal Anti Organ Injury and Improves Surviva 81:939-944 (1988)	l from Hemorrhagic Shock and R	esuscitation in Rab	bits" <u>J. Clin. Invest</u>
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*80	Yates, "Protein Structure Analysi	s by Mass Spectrometry" <u>Method</u>	s in Enzymology 271	:351-377 (1996)
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GENENTECH, INC. GENENTECH, INC. GENENTECH, INC. GENENTECH, INC.



1 DNA Way South San Francisco, CA 94080-4990 (650) 225-4462 TWX 9103717168

LEGAL DEPARTMENT

FAX NUMBERS (650) - 952-9881 OR (650) - 952-9882

DATE: May 28, 2004

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COMMENTS:

Re: Genentech Docket No.: P1089R1C1

Lam et al.

Serial No. 09/724,868

Filed: November 28, 2000

Title: ANTIBODY FORMULATION

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